No. 89-243

In The Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, non-drug products?

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OPINIONS BELOW

The opinion of the Court of Appeals is reported at 872 F.2d 402 (Pet. App. 1a).[1] The Court of Appeals denied a timely petition for panel rehearing on May 31, 1989 (Pet. App. 8a), and issued its judgment as a mandate on June

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[1] Citations in this brief observe the following format. Citations to the Joint Appendix on Writ of Certiorari are in the form of "JA ___." Citations to the Appendix to the petition for a Writ of Certiorari are in the form of "Pet. App. ___." Citations to the trial transcript are by day and page in the form of "Trans. Day ___: ___." Citations to the trial exhibits are in the form of "Tr. Ex. ___."

8, 1989 (Pet. App. 14a). The Court of Appeals declined Lilly's suggestion for rehearing in banc on July 18, 1989 (Pet. App. 9a). The dissenting opinion on the denial of Lilly's suggestion for rehearing in banc is reported at 879 F.2d 849 (Pet. App. 10a).[2]

The memorandum decision of the United States District Court for the Eastern District of Pennsylvania rejecting 35 U.S.C. § 271(e)(1) as a defense to patent infringement for medical devices is reported at 5 U.S.P.Q 2d 1760 (Pet. App. 15a). The district court issued a memorandum decision, 7 U.S.P.Q. 2d 1439, supporting the issuance of a permanent injunction against respondent (Pet. App. 21a). The district court further issued a memorandum decision, 696 F. Supp. 1033, directing that judgment be entered in favor of Lilly (Pet. App. 41a).

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the Court of Appeals was invoked pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1).

The decision of the Court of Appeals was entered on March 29, 1989 (Pet. App. 1a). A timely petition for rehearing was denied on May 31, 1989 (Pet. App. 8a). On August 11, 1989, the Petition for Writ of Certiorari was filed. By order dated October 10, 1989, this Court granted the Petition pursuant to 28 U.S.C. § 1254(1).

STATUTE INVOLVED

35 U.S.C. § 271(e)(1)

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a

[2] This Court (White, Justice) denied Lilly's application to stay the mandate of the Court of Appeals on July 24, 1989. This Court denied Lilly's reapplication to recall and stay the mandate of the Court of Appeals on November 6, 1989.

> new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The full text of 35 U.S.C. § 271(e), including Sections 271(e)(2), (e)(3), and (e)(4), is set forth in petitioner's appendix, pp. 62a-63a, to its certiorari petition.

STATEMENT OF THE CASE

A. Factual Background

Petitioner Eli Lilly and Company ("Lilly") is an Indianapolis-based manufacturer of prescription pharmaceuticals and other products (Pet. App. 22a).[3] Lilly's wholly-owned subsidiary, Cardiac Pacemakers, Inc. ("CPI"), manufactures and sells pacemakers and automatic implantable cardioverter defibrillators (Pet. App. 23a).

Respondent Medtronic, Inc. ("Medtronic") is a Minneapolis-based company (Pet. App. 23a). Medtronic is a leading manufacturer of pacemakers (Pet. App. 24a). Medtronic and CPI are competitors in the pacemaker and automatic implantable cardioverter defibrillator fields. Lilly does not compete in those fields.

[3] Pursuant to Rule 28.1 of the Rules of this Court, Lilly states that it has no publicly-owned parents, subsidiaries, or affiliates.

Lilly holds the exclusive rights to the two patents in suit, U.S. Patent No. Re 27,757 (hereinafter "the '757 patent") and U.S. Patent No. 3,942,536 (hereinafter "the '536 patent") (Pet. App. 23a). Lilly has sublicensed these patent rights to CPI (*id.*).

The '757 patent is for an invention relating to an automatic implantable cardioverter defibrillator (Tr. Ex. 500). This device functions like a miniaturized emergency room which may be implanted in the body of the patient. It automatically monitors the heart through a heart-sensing lead and shocks the heart back to its normal rhythm when conditions of ventricular tachycardia (abnormally fast heartbeat) or ventricular fibrillation (fluttering of the heart muscles) occurs (Pet. App. 23a). The '536 patent is for an invention relating to a special heart-shocking lead (Tr. Ex. 501) designed to carry electrical energy from the cardioverter defibrillator unit to the heart (Pet. App. 23a). With this invention, an automatic cardioverter defibrillator may be implanted with a simple surgical procedure rather than complex open-chest surgery.

In reliance on their patent rights, Dr. Michel Mirowski and his investor toiled for ten years from the time of the invention until the world's first human implant in 1980

of a commercial embodiment of the patented invention[4] (Trans. Day 2: 154-57). It took another five years, until 1985, before the Food and Drug Administration approved the patented product for commercial use (Tr. Ex. 600).

In 1985, Lilly paid the developers of the inventions in suit in excess of $60 million, plus additional royalties, for the exclusive rights to the patented inventions and other assets (Trans. Day 3: 43-45; Tr. Ex. 209). Lilly immediately sublicensed its exclusive patent rights to its wholly-owned subsidiary, CPI (Pet. App. 23a). CPI, but not Lilly, makes, uses, and sells automatic implantable cardioverter defibrillators.

Pursuant to the patent laws, Lilly obtained a two-year extension on the term of the '757 patent, which thus is scheduled to expire on October 26, 1990 (Tr. Ex. 519). Lilly has not received the benefits of a patent extension for the '536 patent, which is scheduled to expire on March 9, 1993.

CPI's embodiment of the invention of the '757 patent has saved the lives of many thousands of patients:

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[4] During the summer of 1967, Dr. Michel Mirowski conceived his invention of the implantable defibrillator (Trans. Day 2: 4-8). Dr. Mirowski left his tenured position in Israel and moved to the United States to obtain the financial support needed to commercialize his invention (Trans. Day 2: 12-13). During 1970, Medtronic expressed an interest and obtained ownership of Dr. Mirowski's patent rights by assignment (Pet. App. 24a). Citing marketing reasons and technological hurdles, Medtronic abandoned the project and returned the patent rights to Dr. Mirowski in 1972 (Pet. App. 24a; Tr. Ex. 173; Trans. Day 2: 30-32). About the same time, a preeminent cardiologist published an article in a widely circulated medical journal which sharply criticized Dr. Mirowski's invention and concept (Trans. Day 2: 38-39; Tr. Ex. 515). Dr. Mirowski persevered. Ultimately, he licensed his patents to a small medical device company, Medrad (later known as Intec Systems, Inc. ("Intec")), with no prior experience in defibrillators or pacemakers (Trans. Day 2: 40-42). For several years thereafter, technical details of the implantable defibrillator were perfected until it was believed suitable for long-term human implantation (Trans. Day 2: 154-59).

> Those patients [without an implantable defibrillator] who survive an episode of sudden cardiac arrest have a survival rate ranging from 30 to 60 percent during the first year after that episode.
>
> Conventional drug therapy is often not capable of treating many surviving patients and preventing an episode of sudden cardiac arrest.
>
> Patients who have survived an episode of ventricular tachycardia or ventricular fibrillation and who receive a CPI implantable defibrillator have a survival rate of 95 to 98 percent for the first year after their initial episode.

(Pet App. 23a-24a).

Sales of the invention have improved dramatically CPI's corporate financial picture (Pet. App. 35a; Trans. Day 3: 52-53, 55-56). The implantable defibrillator patents have given CPI an important technological advantage that has had ripple effects for its entire business. CPI has been able to attract and retain top researchers and engineers who might not have considered CPI in the past (JA 54-55). New customers' doors have been opened to CPI, and other products of CPI have gained acceptance in the medical community (JA 46-47, 54-55). In reliance on the period of exclusivity provided by the patents, CPI has introduced leading physicians to its devices and has trained them in proper device use, patient selection, surgical procedure, and post-surgical care (JA 55, 59-60).

B. Proceedings in the District Court

Pursuant to 28 U.S.C. § 1338(a), Intec brought this suit in the United States District Court for the Eastern District of Pennsylvania against respondent Medtronic. After purchasing certain Intec assets in 1985, Lilly was substituted for Intec as the plaintiff. The complaint alleged that Medtronic's development and marketing of its devices

infringed the two patents in suit. Plaintiff sought damages and injunctive relief.

In 1987, Medtronic raised as a pretrial defense a claim that it made and sold the infringing devices solely for the purpose of obtaining FDA marketing approval, and that 35 U.S.C. § 271(e)(1) immunized this activity.[5] Section 271(e)(1) was enacted in 1984 and provided then as follows:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.[6]

The district court ruled that this section is limited to drugs and does not provide an exemption for infringing medical devices (Pet. App. 15a). The court reasoned that the statute on its face "clearly speaks" solely in terms of drugs (Pet. App. 18a-19a). "Nowhere," the district court concluded, "is there any indication that Congress had a broader intention to include medical devices within the coverage of § 271(e)(1)" (*id.* at 19a).

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[5] Although this lawsuit was initiated in 1983, Medtronic did not raise the Section 271(e)(1) defense until 1987, after Medtronic lost the reexamination proceedings on the patents in suit before the United States Patent and Trademark Office, and nearly two and one-half years after enactment of Section 271(e)(1).

[6] Section 271(e)(1) was amended in 1988 to include certain animal products. Pub. L. No. 100-670, 102 Stat. 3971 (1988). The Court of Appeals stated that the amendment did not affect its analysis (Pet. App. 4a). As shown hereafter, however, the amendment confirms the correctness of the district court's interpretation of the statute.

Following a jury trial, the court granted a directed verdict in Lilly's favor on infringement of the '536 patent, and the jury returned a verdict in Lilly's favor on infringement of the '757 patent, including a jury finding that Medtronic willfully infringed both patents in suit (Pet. App. 22a, 35a). The district court further determined that the patents were valid and enforceable, and it directed that judgment be entered in Lilly's favor (Pet. App. 41a-42a, 55a). The court also entered a permanent injunction against Medtronic's infringement of the Lilly patents (Pet. App. 22a, 40a).

C. Proceedings in the Court of Appeals

On appeal from the injunction pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1), the Court of Appeals reversed and remanded (Pet. App. 1a). The Court of Appeals concluded that Lilly and Medtronic had "put forth equally plausible interpretations of section 271(e)(1)," and it found both the language and legislative history of the statute to be ambiguous (Pet. App. 5a). The court ruled in Medtronic's favor, however, on the basis of an argument the court developed, *sua sponte*.

In the Court of Appeals' view, Section 271(e)(1) should be interpreted by reference not to its language, but to Congress' intent to overrule a prior case involving infringement of a drug patent, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). The Court of Appeals claimed there was a congressional intent to overrule *Bolar* "in all of its ramifications" (Pet. App. 7a), *i.e.*, with respect to numerous other products, including medical devices, food additives, and color additives.

Lilly timely sought rehearing and rehearing in banc. Because of the importance of the court's holding, numerous *amicus* briefs were submitted, not only by manufacturers of medical devices, but also by manufacturers of other FDA-regulated products. Additionally, Senator Orrin G. Hatch,

the principal author of Section 271(e)(1), and Representative Carlos J. Moorhead, a floor manager for the legislation, filed an *amicus* brief supporting Lilly's petition for rehearing. The panel, however, denied rehearing without opinion on May 31, 1989 (Pet. App. 8a).

On July 18, 1989, the Court of Appeals declined Lilly's suggestion for rehearing in banc (Pet. App. 9a). Judge Newman dissented on the grounds of the "exceptional importance" of the case and "the weight of the panel's error" in departing from the clear statutory language (Pet. App. 10a, 13a). Judge Newman indicated that the panel erroneously "held that the statutory words 'drugs and veterinary biological products' include medical devices" (Pet. App. 10a). Judge Newman further stated:

> The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest. Lilly, and *amici* on its behalf, observe that there are different considerations in connection with medical devices, as compared with human and animal drugs. Congress would be expected to consider the public and private economic and policy aspects of these complex industries. I cannot imagine how, on the record before us, a panel of this court can decide how Congress will decide the issue. *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) ("It is not the function of the court to amend statutes under the guise of 'statutory interpretation' ").

(Pet. App. 12a-13a) (footnote omitted).

SUMMARY OF THE ARGUMENT

The decision below interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984.[7] That provision, codified at 35 U.S.C. § 271(e)(1), states that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs*" (emphasis added). As both the statute's terms and the legislative history make clear, Congress never intended the statute to apply to non-drug products.

The decision below applies the exemption in Section 271(e)(1) to a wide spectrum of non-drug products not named in the statute, including medical devices, color additives, food additives, and other products regulated by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. The Court of Appeals concluded, *sua sponte*, that Section 271(e)(1) should be interpreted by reference not to its language, but to Congress' intent to overrule a prior case involving infringement of a *drug* patent, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

The Court of Appeals' decision contravenes the plain language of Section 271(e)(1), its legislative history, and sound public policy. The statute expressly restricts its application to uses relating solely to the development of information for submission under "a Federal law which regulates . . . drugs." By its terms, this refers to submissions under 21 U.S.C. § 355, the federal statute prohibiting introduction of a new drug into interstate commerce without prior approval by the FDA. It would be odd, to say the least, for Congress to identify the premarket approval requirements for medical devices, food additives, and color

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[7] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

additives as being set forth in a law "which regulates . . . drugs."

Had Congress intended to apply Section 271(e)(1) to medical devices and other FDA-regulated articles in addition to drugs, it would have identified submissions under the "Federal Food, Drug, and Cosmetic Act"–a term used only a few lines earlier in the same subsection. It conflicts with basic tenets of statutory construction to assume that Congress used a different (and facially more restrictive) term to refer to the same Act elsewhere in Section 271(e)(1). Congress would have continued to identify the Federal Food, Drug, and Cosmetic Act by name in the operative language of Section 271(e)(1) if it in fact intended the infringement exemption to apply to any use under that Act.

Other provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 demonstrate that Congress intentionally limited Section 271(e)(1) to drugs. For example, the companion Sections 271(e)(2) and (e)(4), which qualify Section 271(e)(1), indisputably are restricted to the enumerated products, *i.e.*, drugs and veterinary biological products. Section 271(e)(1) must be construed in the same manner. Within the same Act, Congress expressly included drugs, medical devices, food additives, color additives, and veterinary biological products in 35 U.S.C. § 156(f), while expressly identifying only drugs and veterinary biological products in Section 271(e)(1). This disparate inclusion and exclusion demonstrates that Congress purposely excluded medical devices from Section 271(e)(1).

Since the statutory language is clear, there was no reason for the Court of Appeals to examine the legislative history of Section 271(e)(1). Having done so, however, the court below seriously misconstrued that history. Each of the statements referring expressly to the class of products affected by Section 271(e)(1) indicates that Congress

intended it to apply solely to drugs. There is not a single statement in the legislative history suggesting that any legislator believed that it would apply to medical devices or other non-drug products. Generalized references to overruling the holding of the *Bolar* case--which itself involved a drug patent, not a device patent--are no basis for disregarding the statutory language and specific statements in the legislative history as to the scope of Section 271(e)(1). Congress understood the holding of that case to relate only to drugs, and the Court of Appeals should have interpreted the statute consistent with Congress' understanding.

Finally, there is a sound policy basis for distinguishing between drug and device patents in Section 271(e)(1). The premarket bioequivalence testing required for approval of generic copies of patented drugs is quite limited by comparison with the extensive clinical trials required for approval of new medical devices such as CPI's implantable defibrillator. Drug bioequivalence testing is conducted in a small number of healthy volunteers, and does not take customers away from the patent holder. Device testing, by contrast, requires testing in patients with the disease or condition under study, and clinical trials may take away millions of dollars in sales from the device patent holder. Such losses can be expected to stifle device innovation, to the detriment of the public health. For these reasons, the fact that Congress authorized limited drug testing prior to patent expiration is no basis for presuming that Congress also intended to permit the much greater inroads on patent rights that pre-expiration device testing would entail.

The decision below is quite clearly wrong. It constitutes impermissible judicial legislation to expand the limited scope of Section 271(e)(1).

ARGUMENT

This is not an ordinary patent case. It involves the construction of a federal statute that will have, unless reversed, a significant negative impact on investment in health-care research and development, and on the pace of innovation in lifesaving medical devices. Medical devices are subject to premarket approval and other regulation by the FDA. Prior to the Court of Appeals' decision in this case, it would have been an act of patent infringement to make, use, or sell an infringing product in studies conducted to obtain the data necessary for FDA approval for medical devices or other non-drug products. The Court of Appeals interpreted a narrow statutory exemption, which universally had been understood to apply *only* to the limited testing necessary for generic drug approvals (JA 27-28), to encompass studies for *all* FDA-regulated products. That decision is incorrect as a matter of law.

I. The Statutory Language Expressly Limits Section 271(e)(1) to Drugs and Veterinary Biological Products and Does Not Encompass Medical Devices and Other FDA-Regulated Products

A. The Plain Meaning of the Statute Is Directly Contrary to the Court of Appeals' Decision

The United States patent laws broadly provide that "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). In its present form, 35 U.S.C. § 271(e)(1) provides a limited exception to the broad infringement statute:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug,

> and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably *related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products* (emphasis added).

35 U.S.C. § 271(e)(1).[8]

"Interpretation of a statute must begin with the statute's language." *Mallard v. U.S. District Court for the Southern District of Iowa*, ___ U.S. ___, 109 S.Ct. 1814, 1818 (1989). The ordinary reading of the quoted statutory language grants a narrow exemption from patent infringement for developing information necessary to obtain approval for "drugs" and "veterinary biological products," the specifically enumerated categories. "Medical devices" are not mentioned. Indeed, medical devices are expressly excluded from the definition of the term "drug" under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 321(g)(1) ("The term 'drug' . . . does not include devices or their components, parts, or accessories."). Drugs and devices are regulated under entirely different statutory

[8] The statute initially referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary biological products" was added in 1988. Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988). While subsequent amendments cannot substitute for a clear expression of legislative intent at the time of enactment, "they should not be rejected out of hand as a source that a court may consider in the search for legislative intent." *Andrus v. Shell Oil Co.*, 446 U.S. 657, 666 n.8 (1980). Here, the subsequent amendments confirm that Section 271(e)(1) is product specific, excluding medical devices.

provisions. *Compare* 21 U.S.C. § 355 (drugs) *with* 21 U.S.C. § 360 (devices).

This should have been the end of the matter. The courts are bound by the specific statutory language in construing statutory provisions. *See, e.g., United States v. James*, 478 U.S. 597, 604-606 (1986). Inexplicably, however, the Court of Appeals has read the provision to grant an exemption from patent infringement not only for drugs and veterinary biological products, but also for developing information necessary to obtain approval of a wide spectrum of other products requiring FDA approval, most significantly, medical devices.[9]

The Court of Appeals' interpretation undeniably requires a strained reading of the plain language of the statute.[10] To bring medical devices within the ambit of the statute, it is necessary to find that the phrase "related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" is shorthand for the entire Federal Food, Drug, and Cosmetic Act, *including the device provisions*, as well as the Biologics Act of 1902. This reading is directly refuted by the plain language of the statute: a few lines earlier in Section 271(e)(1), Congress referred expressly to the

[9] The Court of Appeals' reading also effectively changes patent infringement law with respect to food additives and color additives. *See* 21 U.S.C. §§ 348, 376; 21 C.F.R. §§ 71.1, 171.1 (1988) (describing data submission requirements for food additive petitions and color additive petitions).

[10] The Court of Appeals' reliance on *United States v. Fausto*, 484 U.S. 439 (1988) (Pet. App. 6a), does not support its departure from the statutory language. Rather, that case confirms the importance of both the language chosen by Congress and the congressional intent. The instant case raises no question requiring the reconciliation of interrelated laws enacted at different times. Rather, it requires only a straightforward exercise in the interpretation of Section 271(e)(1) based on its plain language and legislative history.

"Federal Food, Drug, and Cosmetic Act." The Court of Appeals' reading cannot be squared with the language of Section 271(e)(1).

In contrast with petitioner's straightforward reading of the statute, the Court of Appeals erred by giving, in effect, the same meaning to different phrases in the same statute. It is unreasonable to assume that Congress used the term "law which regulates . . . drugs" to mean the entire Federal Food, Drug, and Cosmetic Act, when it identified the statute by name in Sections 271(e)(1) and (e)(2). *See, e.g., Colautti v. Franklin,* 439 U.S. 379, 392-93 (1979) (rejected theory that "may be viable" means "viable" within the same statute); *Russello v. United States,* 464 U.S. 16, 23 (1983) (rejected argument that differing language in two subsections of a statute had the same meaning); *National Insulation Transportation Committee v. Interstate Commerce Commission,* 683 F.2d 533, 537 (D.C. Cir. 1982) ("the use of different terminology within a statute indicates that Congress intended to establish a different meaning"). In short, if Congress had meant to exempt any experimental use of medical devices for premarket approval under the Federal Food, Drug, and Cosmetic Act, it would have said so expressly. The Court of Appeals erred by concluding otherwise.

The decision below also is inconsistent with the holdings of the few courts that have considered the issue prior to the ruling. The district court in the instant case, as well as the only other district court to have discussed the issue, concluded that Section 271(e)(1) is limited to drugs. *See* Pet. App. at 19a ("the § 271(e)(1) defense [is] inapplicable to medical devices"); *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.,* 7 U.S.P.Q. 2d 1562, 1565 (D. Del. 1988) ("It is also clear that Section 271(e)(1) applies only to drugs, not to medical devices." (dictum citing the district court's decision in this case)).

B. The Remaining Sections of 35 U.S.C. § 271(e) Limit Section 271(e)(1) to Drugs and Veterinary Biological Products

The argument for a broad construction of Section 271(e)(1) is refuted by the companion Sections (e)(2) and (e)(4). Sections 271(e)(2) and (e)(4) qualify Section 271(e)(1). *Scripps Clinic and Research Foundation v. Genentech, Inc.,* 231 U.S.P.Q. 978, 980 (N.D. Cal. 1986) (Section 271(e)(2) "limits the scope of the preceding [Section 271(e)(1)]"); *Eli Lilly and Company v. Premo Pharmaceutical Laboratories,* 4 U.S.P.Q. 2d 1080, 1083 (D.N.J. 1987), *aff'd,* 843 F.2d 1378 (Fed. Cir. 1988) ("Section 271(e)(2) qualifies [Section 271(e)(1)]"). These sections indisputably are restricted to specifically-identified products, *i.e.,* drugs and veterinary biological products.

Congress included protections–by specifying acts of infringement and establishing remedies–for drug patent holders under certain circumstances in Sections 271(e)(2) and (e)(4) (Pet. App. 62a-63a). Congress added similar protections for owners of patented animal products in the 1988 amendment to Section 271(e) (*id.*). Had Congress intended medical devices to fall within the infringement exemption of Section 271(e)(1) as originally enacted, surely Congress would have provided corresponding protections for patent holders of medical device inventions in the original enactment of Sections 271(e)(2) and (e)(4).[11] However, the current Sections 271(e)(2) and (e)(4) are specific to "drugs" and "veterinary biological products" and thus further confirm that their companion Section 271(e)(1)

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[11] For example, proposed Senate Bill S.622 would add "medical devices" to Sections 271(e)(1), (e)(2) and (e)(4) (Pet. App. 60a-61a). After-the-fact congressional activity is no substitute for the statutory language and congressional intent at the time of the enactment for purposes of statutory interpretation. However, the subsequently proposed bill is consistent with the 1984 enactment.

should be construed in the same manner. *See, e.g., Sedima S.P.R.L. v. Imrex Company, Inc.*, 473 U.S. 479, 489 (1985) ("should not lightly infer that Congress intended the term to have wholly different meanings in neighboring subsections").

The Court of Appeals' decision inserts the words "medical devices" into Section 271(e)(1) without providing the additional patent protections of Sections 271(e)(2) and (e)(4). This is the worst possible result for medical device patent holders and was never expressed or intended by Congress.

C. Other Provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 Demonstrate that Section 271(e)(1) Was Limited Intentionally to Drugs

Congress added Section 271(e)(1) to the patent statute as part of a broader enactment.[12] Courts must interpret the various sections of the same law, concerning the same subject, together to avoid conflicts and to assure consistency. *See, e.g., United States v. Morton*, 467 U.S. 822, 828 (1984); *In re Nantucket, Inc.*, 677 F.2d 95, 98 (C.C.P.A. 1982). In both the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act") and the Federal Food, Drug, and Cosmetic Act ("FD&C Act") to which the 1984 Act refers, Congress distinguished between "drugs" and "devices." *See* pages 13-15, *supra*. This Court should construe Section 271(e)(1) together with the other provisions of the 1984 Act and the FD&C Act.

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[12] On September 24, 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. Pub L. No. 98-417, 98 Stat. 1585 (1984). The 1984 Act consists of two relevant titles: Title I addresses "Abbreviated New Drug Applications" (ANDA), and Title II covers "Patent Term Restoration." Title II of the 1984 Act is relevant because it amended the Patent Act by adding 35 U.S.C § 271(e) and 35 U.S.C. § 156.

In the patent extension provisions of the 1984 Act, when Congress intended to extend the patent life for inventions covering both drugs and medical devices, it said so expressly. Congress explicitly stated that the patent extension provisions apply to "products" subject to a regulatory review period before commercial marketing or use. 35 U.S.C. § 156(a)(4). Congress then expressly identified the products involved:

> (A) A human drug product.
>
> (B) Any medical device, food additive, or color additive subject to regulation under the *Federal Food, Drug, and Cosmetic Act*.

35 U.S.C. § 156(f)(1) (1984) (emphasis added). It is noteworthy that the phrase used in Section 271(e)(1)–"a Federal law which regulates the manufacture, use, or sale of drugs" was not used. Instead, Congress used the phrase "under the Federal Food, Drug, and Cosmetic Act."

If Congress had intended to provide an infringement exemption for devices as well as for drugs, it would have referred to a law which regulates "drugs *and* devices." Whenever Congress limited a patentee's rights under Section 271(e)(1) or provided patent extension rights

under Section 156, Congress spoke clearly.[13] Congress used clear language to identify "drugs" under the Section 271(e)(1) exemption and the Section 156 extension provisions in the 1984 original enactment. Congress used clear language to identify that under limited circumstances, medical device, food additive, and color additive patents qualified for patent extensions under Section 156. Congress' 1988 amendment of the statute extended the exemption and patent extension rights to certain animal drugs and veterinary biological products. Congress did so by adding the express reference to "veterinary biological products" and deleting the exclusion for certain animal drugs from the "drug" category in Sections 271(e) and 156. *See* Pub. L. No. 100-670, 102 Stat. 3971, 3988 (1988).

"[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello*, 464 U.S. at 23 (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972). Within the same Act, Congress expressly included drugs, veterinary biological products, medical devices, food additives, and color additives in 35 U.S.C. § 156(f) while expressly identifying only drugs and veterinary biological products in 35 U.S.C. §§ 271(e)(1), (e)(2) and (e)(4). This disparate inclusion and exclusion is no accident.[14] The principle of statutory construction espoused in *Russello* controls, and Section 271(e)(1) must be interpreted to exclude purposely medical devices, food additives, and color additives.

[13] Section 271(e)(1) is not a *quid pro quo* accepted for the enactment of 35 U.S.C. § 156, the patent extension provisions of the Patent Act. The legislation that eventually led to enactment of 35 U.S.C. § 156 had been before Congress since 1980, well before the 1984 *Roche* decision which prompted enactment of Section 271(e)(1). *See* S.2892, 96th Cong. 2d Sess. (1980). Moreover, the two statutes are not, and never were intended to be, coextensive. Section 271(e)(1) applies even during the original term, and not just to the extended term, of patents that have been extended. Section 271(e)(1) also applies to many patents that do not meet the numerous eligibility requirements for extension under Section 156(a). *Cf. Fisons v. Quigg*, 872 F.2d 99 (Fed. Cir. 1989) (discussing eligibility restrictions). As is the case generally with the vast majority of medical device patents, Lilly has not received the benefits of a patent extension for the '536 patent. However, Lilly has lost its exclusive rights to the '536 patent under Section 271(e)(1) as construed by the Court of Appeals.

D. The Operative Language of Section 271(e)(1) Is Not "Patented Invention" as Alleged by Respondent

The term "patented invention" is the term used in 35 U.S.C. § 271(a) which Section 271(e)(1) modifies. Section 271(e)(1) follows a similar form. However, the operative language of Section 271(e)(1) is the phrase "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." This operative language modifies and restricts the term "patented invention" within the Section 271(e)(1) exemption.

Although the Court of Appeals did not accept the argument, Medtronic urged below that the statutory language was ambiguous because Congress referred to the term "patented invention" rather than to the terms "drug" or "patented human drug product." In its brief in opposition to Lilly's petition for a writ of certiorari, Medtronic changed its argument. Medtronic now says Congress could have used the term "drug invention" (Respondent's Brief in Opposition, p. 8).

[14] The district court held that "other sections of the [Drug Price Competition and Patent Term Restoration Act of 1984] distinguish between 'drugs' and 'devices,' further indicating that when Congress intended to include devices within the coverage of a section, it clearly specified as much, rather than assume the term 'drugs' to include 'devices' "(Pet. App. 18a).

The use of the term "patented invention" is explicable because Congress was dealing not only with product patents but also with patents for drug compositions and patents for uses of drugs. Thus, the terms "patented drug" or "drug invention" would have been potentially unclear as to whether it was limited to product patents, whereas the term "patented invention" covers patents for drug products, as well as drug composition and drug use. In addition, the use of the term "patented invention" is consistent with 35 U.S.C. § 271(a).

II. The Court of Appeals Misused the Legislative History to Reach a Decision Inconsistent with Congress' Clear Language and Intent

The Court of Appeals erred by disregarding the plain language of Section 271(e)(1) in favor of a broader policy allegedly expressed in the legislative history. *See, e.g., Burlington Northern Ry. Co. v. Oklahoma Tax Comm'n,* 481 U.S. 454, 461 (1987) (in the absence of ambiguity, statutory language is conclusive). There is no ambiguity in Section 271(e)(1). The phrase "under a Federal law which regulates the manufacture, use, or sale of drugs" cannot mean "under a Federal law which regulates the manufacture, use, or sale of drugs *and medical devices.*" The Court of Appeals and Medtronic use isolated statements in the legislative history not to resolve doubt, but to create it. *See, e.g., Railroad Commission of Wisconsin v. Chicago B. & Q. Ry. Co.,* 257 U.S. 563, 589 (1922) ("[Committee reports] are only admissible to solve doubt and not to create it.").

In any event, the legislative history contradicts the Court of Appeals' decision and further demonstrates that Congress intended for Section 271(e)(1) to allow limited infringement only for drugs (and later for animal products), but not for any other FDA-regulated product. There is not a single reference in the legislative history of this provision

suggesting the possibility of exempting infringement of medical device patents.

Two committee reports were prepared on the 1984 legislation originally enacting Section 271(e)(1): one by the House Committee on Energy and Commerce and one by the House Committee on the Judiciary. H.R. Rep. No. 857, 98th Cong., 2d Sess. Parts 1 and 2 (1984). Both reports unambiguously establish that Section 271(e)(1) is directed solely to drugs.

The Committee on Energy and Commerce stated:

> The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug product,* when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of [A]ppeals for the Federal Circuit held that this type of experimentation is infringement.
>
> In *Roche* . . ., the Court of Appeals for the Federal Circuit held that the experimental use *of a drug product* prior to the expiration date of a patent claiming that *drug product* constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires.

H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1, at 45-46 (1984) (emphasis added). *See, e.g., id.,* Part 1, at 15 ("Title II provides that it is not an act of patent infringement for a *generic drug* maker to import or to test a *patented drug* in preparation for seeking FDA approval" (emphasis added)); *id.,* Part 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval of *the drug.*" (emphasis added)); *id.,* Part

2, at 27 n.18 (it would not be infringement to make, use, or sell a patented invention "for the purpose of obtaining FDA premarketing approval of *a drug*" (emphasis added)); *id.*, Part 2, at 29 (provision "permit[s] the limited testing of *drugs* while they are on patent" (emphasis added)). Similarly, the legislative history of the amendment expanding the exemption to animal products describes Section 271(e)(1) as a provision that "applies to *human pharmaceuticals*." S. Rep. No. 448, 99th Cong., 2d Sess. at 13 (1986) (emphasis added).[15]

The Court of Appeals inexplicably dismissed these clear expressions of congressional intent as merely "general statements . . . which allegedly support" the district court's interpretation of the statute (Pet. App. 5a). At the same time, its opinion (*id.*) gives the erroneous impression, without citation, that there are contrary statements supporting the extension of Section 271(e)(1) to devices. There are none. *See* Pet. App. 5a-7a.

The Court of Appeals concluded *sua sponte,* however, that Section 271(e)(1) was intended to overrule the *Bolar* case, *supra,* "in all of its ramifications" (id. at 7a) and thereby to immunize infringement for medical devices and other products not mentioned in the statute itself, in its legislative history, or in the *Bolar* case. This interpretation defies comprehension and is contrary to accepted principles of statutory construction.

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[15] Commentators on the 1984 legislation agreed that this provision "is limited to human drug products, and does not include medical devices . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984,* 40 Food Drug Cosm. L. J. 269, 308 (1985); JA 24-28; *accord,* Fox & Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984,* at 178, 187 (Food and Drug Law Inst. 1987).

Congress intended Section 271(e)(1) to "have the net effect of reversing the *holding*" in *Bolar*. H.R. Rep. No. 857, *supra,* Part 2, at 27 (emphasis added). Congress understood the court in that case to have "held that the experimental use of a *drug product* prior to the expiration date of a patent claiming that *drug product* constitutes patent infringement." *Id.*, Part 1, at 45-46 (emphasis added); *accord, id.*, Part 2, at 27 n.18. In *Bolar* itself, the Court of Appeals stated that the issue was a "narrow" one:

> does the limited use of a *patented drug* for testing and investigation strictly related to FDA *drug* approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

733 F.2d at 861 (emphasis added). Whatever the Court of Appeals now believes its holding to have been, surely it is Congress' understanding at the time it enacted Section 271(e)(1) that is relevant.[16] Thus, Congress overruled *Bolar* "in that (Section 271(e)(1)) would provide that the generic *drug* manufacturers can start playing around with the *drug* on which the patent is about to expire." 130 Cong. Rec. H8712 (daily ed. Aug. 8, 1984) (statement of Rep. Kindness) (emphasis added).

It is difficult to imagine how Congress could have made its intentions any more clearly known. There is simply no basis for concluding that Congress intended anything more than to overrule the precise holding of *Bolar* as Congress

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[16] "The meaning and effect of legislation whose operation is conditioned by common-law principles *are not changed by subsequent judicial decisions* modifying the common-law principles." 2a *Sutherland Statutory Construction* § 50.02, at 431 (4th ed. 1984) (emphasis added). *See generally, e.g., Mackey v. Lanier Collections Agency & Service, Inc.,* 486 U.S. 825, 108 S.Ct. 2182, 2191 (1988) (" 'It is the intent of the Congress that enacted [the section] . . . that controls.' ") (citations omitted).

and the *Bolar* court understood it, *i.e.*, a prohibition on the experimental use of patented drugs for FDA approval purposes. The Court of Appeals here pointed to no evidence of congressional intent, and there is none, suggesting a desire to overrule *Bolar* "in all of its ramifications."[17] The court's *ipse dixit* thus entirely ignores the plainly expressed intention of Congress.

III. The Court of Appeals' Decision Constitutes Impermissible Judicial Legislation

The Court of Appeals' error is all the more apparent because its reading is not limited to devices. It applies also to every other article regulated under the FD&C Act, such as food additives, color additives, and other substances—none of which is referred to anywhere in the infringement exemption of Section 271(e)(1) or in the protections afforded patent holders in Sections 271(e)(2) and (e)(4). In short, the Court of Appeals expanded a statute that by its terms allowed only a narrow infringement exemption for two specifically enumerated products—drugs and veterinary biological products—to apply to medical devices and other products not mentioned anywhere in the statute itself.

The Court of Appeals' decision seems to be based upon its own view of possibly applicable policy considerations (Pet. App. 7a, 13a). The Court, however, was not free to substitute its policy choices for those of Congress and

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[17] Moreover, if Congress intended to overrule all of the "ramifications" of *Bolar*, this would eliminate the experimental-use exception to patent infringement for all inventions, not just for those pertaining to FDA-regulated products. *See Bolar*, 733 F.2d at 862-63. Congress of course intended no such thing, and not even the Court of Appeals suggests that it did. Yet the court offered no justification for picking and choosing among the various "ramifications" of *Bolar* that purportedly were overruled by Section 271(e)(1). The only interpretation that can be defended on the basis of the statutory language and legislative history is that Congress intended to overrule *Bolar* as it applied to drugs.

rewrite the legislation.[18] *See, e.g., United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy."); *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456 (1984), ("it is not our job to apply laws that have not yet been written"); *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply

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[18] The extent of the Court of Appeals' departure from both the words of the statute and Congress' expressed intent is suggested by the fact that its interpretation, extending Section 271(e)(1) to medical devices and other products, was totally unexpected by those in the medical device manufacturing community familiar with the statute. *See amicus* briefs supporting Lilly's petition for certiorari. The Declaration of Peter Barton Hutt, who represented the Pharmaceutical Manufacturers Association in consideration of this legislation and served as a moderator at the Food and Drug Law Institute's briefing on the Drug Price Competition and Patent Term Restoration Act, sets forth the contemporaneous industry involvement regarding Section 271(e)(1) (JA 16, 27-28). The legislative history of Section 271(e)(1) made no reference at all to medical devices, and the medical device industry had no input on the issues relevant to applying Section 271(e)(1) to medical devices (JA 28).

If Congress had intended to include medical devices within the ambit of Section 271(e)(1), it is inconceivable that medical device patent holders would have had no involvement in the process and no opportunity to provide Congress with information on the significant, adverse effects of such legislation on a vitally important high technology industry and on the public. The conclusion that there would have been input from the medical device industry if Section 271(e)(1) was intended to reach medical devices is reinforced by the fact that the legislative history of the 1984 legislation clearly shows that Section 271(e)(1) was drafted after extensive input from both generic and innovator *drug* manufacturers. *See, e.g.*, 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement or Rep. Gore) (legislation "has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, . . . [and] the innovators of new drugs"); *id.* at H8706-07 (daily ed. Aug. 8, 1984) (statements of Reps. Kastenmeier and Waxman).

statutes on the basis of what Congress has written, not what Congress might have written.").

As Judge Newman concluded, the Court of Appeals' departure from the statutory language constitutes impermissible judicial legislation (Pet. App. 12a). The Court of Appeals did not heed this Court's earlier warning:

> Our individual appraisal of the wisdom or unwisdom of a particular course consciously selected by the Congress is to be put aside in the process of interpreting a statute. Once the meaning of an enactment is discerned and its constitutionality determined, the judicial process comes to an end. We do not sit as a committee of review, nor are we vested with the power of veto.

Tennessee Valley Authority v. Hill, 437 U.S. 153, 194-95 (1978).

IV. Public Policy and Constitutional Considerations Require Reversal of the Court of Appeals' Decision

The application of Section 271(e)(1) only to drugs, which is compelled by its language as well as its legislative history, is further supported by important distinctions between FDA regulation of drugs and medical devices.[19] While the Court

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[19] Petitioner is well aware of this Court's holding:

> Since our present task is one of statutory construction, questions of public policy cannot be determinative of the outcome unless specific policy choices can be attributed to Congress itself.

Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 220-21 (1980). However, Lilly feels compelled to address the Court of Appeals' statement that there is "[n]o persuasive reason . . . why Congress would create an exception with respect to those activities for drugs only . . . ." (Pet. App. 7a). The distinctions between the FDA regulations for drugs and medical devices also demonstrate the constitutional problems associated with the Court of Appeals' interpretation.

of Appeals claimed to discern "[n]o persuasive reason . . . why Congress would create an exception with respect to those activities for drugs only . . ." (Pet. App. 7a), there are in fact sound policy considerations favoring this interpretation. The court apparently failed to appreciate these reasons because it lacked a sufficient understanding of the very different FD&C Act provisions and FDA regulations that govern testing and approval of drugs versus medical devices. *See* Judge Newman's dissenting opinion, Pet. App. 12a ("there are different considerations in connection with medical devices, as compared with human and animal drugs"). The extension of the infringement exemption to medical devices is unsupported as a matter of sound policy and serves only to retard the development of innovative health products.

New drugs are subject to premarket approval by the FDA upon a showing of safety and effectiveness. *See* 21 U.S.C. § 355. Prior to 1984, generic copies of previously-approved drugs generally required their own approvals resting on their manufacturers' own clinical studies. *See United States v. Generix Drug Corp.,* 460 U.S. 453 (1983). The same statute that enacted Section 271(e)(1) also established an "abbreviated" procedure for approval of generic drugs. *See* 21 U.S.C. § 355(j). Under this procedure, an applicant for generic approval is not required to submit independent proof of safety and effectiveness, but need show only that its product is "bioequivalent" to the previously-approved drug–i.e., that it has the same "rate and extent of absorption" into the bloodstream. 21 U.S.C. § 355(j)(7)(B)(i).

Section 271(e)(1) permits such bioequivalence testing prior to the expiration of a drug patent. This testing is conducted in a limited number of volunteers, typically healthy persons who do not even have the disease for which the drug is intended. These persons are not charged for the drug. Congress found that the "nature of the interfer-

ence" with a drug patent holder's rights entailed by such bioequivalence testing "is *de minimis*." H.R. Rep. No. 857, Part 2, at 30.[20]

The interference with a medical device patent holder's rights, however, is far more significant. There is no "abbreviated" procedure for premarket approval of medical devices. See 21 U.S.C. § 360. The medical device testing that would be permitted under the Court of Appeals' decision therefore encompasses full-scale clinical trials rather than the much more limited bioequivalence testing necessary for generic drug approval.

Medical device clinical trials permit manufacturers to introduce their products to the market by treating patients with the underlying disease (JA 39-42). Leading physicians and medical institutions are involved in the studies (JA 146). Many devices, such as the implantable defibrillators at issue here, are permanently implanted and thus each patient who is treated with the investigational device is unavailable as a customer to the patent holder. Similarly, many devices, such as diagnostic instruments, have only a small number of potential customers. Hospitals, for example, may need only one CAT-scan machine, and thus each hospital using an infringing device, even for "investigational" purposes, is lost to the patent holder's market.

Moreover, manufacturers charge for investigational devices, even those that infringe patents. *See* 21 C.F.R. § 812.7(b). Such charges are common, especially for expensive devices such as implantable defibrillators. Medtronic, for

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[20] While the statute also would permit clinical trials of patented drugs, Congress understood that, as a practical matter, manufacturers would take advantage of the much faster and less expensive "abbreviated" procedures which require only bioequivalence testing, rather than undertaking their own time-consuming clinical tests in hundreds or thousands of patients. *See* H.R. Rep. No. 857, Part 2, at 8.

example, sold its infringing units for $17,000 each and originally projected (but did not achieve) eleven million dollars of infringing sales—all, according to Medtronic, during clinical trials. (Pet. App. 12a n.4). Some medical devices may carry even higher per-item prices. Indeed, a single medical device itself may be sold for a quarter of a million dollars or more. Clinical trials by infringers could rob patent holders of millions of dollars in lost sales, while the infringers themselves recover all of their "costs of manufacture, research, development, and handling" (21 C.F.R. § 812.7(b))—all before the life of the patent has expired.

Accordingly, there are persuasive reasons–rooted in the different testing procedures and approval requirements of drugs and devices–for distinguishing between them in Section 271(e)(1).[21] Those differences raise a serious constitutional question under the takings clause of the Fifth Amendment of the U.S. Constitution if the statute is interpreted to authorize the infringing use of medical devices. *Cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1018-19 (1984). Section 271(e)(1), as interpreted by the Court of Appeals, impermissibly takes a portion of the exclusive patent rights from medical device patent holders *after* a patent holder has disclosed its invention to the public. Such public disclosure is the *quid pro quo* for the exclusive patent right for the *entire* patent term. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, ___ U.S. ___, 109 S.Ct. 971, 977 (1989)

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[21] Although not adopted by the Court of Appeals, Medtronic alleges that the district court's interpretation of Section 271(e)(1) results in a *de facto* extension of certain patents. Medtronic could have avoided any alleged *de facto* extension of the patents in suit. Medtronic's expert trial witness, Mr. Paul Wylie, testified under oath that Medtronic can easily obtain FDA approval prior to patent expiration based on activities outside the United States that would not infringe the patents in suit (JA 107-8). *See also* 21 C.F.R. § 814.15 (regulations permit FDA approval of medical devices based solely on foreign activities).

("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").

When it enacted Section 271(e)(1), Congress addressed this takings question as it applied to drugs, and it concluded that the statute was constitutional largely because of the "de minimis economic impact" on drug patent holders:

> [T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. . . . Thus, the nature of the interference with the rights of the patent holder is not substantial.

H.R. Rep. No. 857, Part 2, at 8; *see also id.*, Part 2, at 27-30; *id.*, Part 1, at 46 (Bioequivalence is equivalence in the rate and extent of absorption of a drug. *See* 21 U.S.C. § 355(j)(7)(B)(i)).

The much more substantial economic impact of an infringement exemption for medical devices raises a correspondingly more substantial constitutional issue. That issue would be avoided, as it should be, by interpreting Section 271(e)(1) in accordance with its plain meaning and legislative history to apply only to drugs and veterinary biological products. *See generally Ashwander v. Tennessee Valley Authority,* 297 U.S. 288, 346-348 (1936) (Brandeis, J., concurring); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council,* 485 U.S. 568, 108 S.Ct. 1392, 1397 (1988) ("where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress").

Finally, the Court of Appeals' decision will have a significant deleterious effect on medical device innovation, and therefore on public health. The patent system is intended to provide the necessary incentive for "inventiveness and research efforts." *Diamond v. Chakrabarty,* 447 U.S. 303, 307 (1980). That incentive would be seriously eroded if infringement is immunized for device testing purposes.

The decision below will discourage precisely what the patent laws are intended to encourage–innovation, technological development, and investment in high-risk ventures, such as the automatic implantable cardioverter defibrillator. The absence of full patent protection will encourage copying instead and merely benefit the imitators of innovators.

At the same time that it enacted Section 271(e)(1), Congress provided for the partial extension of drug and device patents in order to "create a significant, new incentive which would result in increased expenditures for research and development" in the health-care industry. H.R. Rep. No. 857, *supra,* Part 1, at 18. While Congress was willing, as part of a compromise with generic drug interests, to make a *de minimis* exception for drug bioequivalence testing, it did not make the much larger inroad on patent rights that a device exception would represent. Such an exception would eviscerate the very research incentives that Congress had intended to expand in the 1984 legislature. As Judge Newman concluded, "[t]he panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest" (Pet. App. 12a).

CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Appeals for the Federal Circuit should be reversed, and this case should be remanded with instructions to enter judgment in favor of the petitioner and to reinstate the district court's original injunction.

Respectfully submitted,

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